

REMARKS

Interview request

Applicants respectfully request a telephonic interview after the Examiner has reviewed the instant response and amendment. Applicants request the Examiner call Applicants' representative, as noted below.

Status of the Claims

*Pending claims*

Claims 1 to 26 are pending.

*Claims added in the instant amendment*

In the present response, claims 27 to 31 are added. Thus, after entry of the instant amendment, claims 1 to 31 will be pending and under consideration.

*Allowable Subject Matter*

Applicants thank the Examiner for noting that there is allowable subject matter, as discussed in detail in the OA, paragraph 17, page 19. See new claims 27 to 31.

*Outstanding Rejections*

Claims 1, 3, 4, 7 to 11, 19, 20 and 22 to 26, are rejected under 35 U.S.C. §102(e) as allegedly anticipated by Siddiqui-Jain, et al., U.S. patent application publication no. 2004/0005601 A1, having a priority date of April 05, 2002. Claims 19 and 20 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kerwin, et al., U.S. Patent No. 6,156,763, filed February 4, 1999. Claims 1, 3, 5 to 7, 10, 11 and 21, are rejected under 35 USC §103(a) as allegedly unpatentable over Kerwin, in view of Matsugami, et al., J. of Molec. Biol. 313:255-269, Oct. 2001. Claims 5, 6 and 21, are rejected under 35 USC §103(a) as allegedly unpatentable over Siddiqui-Jain, et al., the '5601 publication, in view of Matsugami.

Applicants respectfully traverse all outstanding objections to the specification and rejection of the claims.

Support for the claim amendments

The specification sets forth an extensive description of the invention in the new and amended claims. Accordingly, no new matter has been added by way of these amendments.

The Group Restriction Requirement

The Patent Office alleged that the pending claims of the application are directed to two separate and distinct inventions under 35 U.S.C. §121, as set forth on pages 2 to 3, paragraphs 1 and 2, of the OA (including reasons for the Group election as set forth, inter alia, on page 4, paragraph 4, of the OA):

Group I, including inter alia, claims 1 to 11 and 19 to 26, drawn to, inter alia, methods of identifying a molecule that interacts with quadruplex DNA, identifying a quadruplex structure in a sample, and identifying a nucleotide sequence capable of forming a quadruplex structure, classified in, inter alia, class 435, subclass 6;

Group II including inter alia, claims 12 to 18, drawn to a method for modulating the biological activity of a biologically significant native quadruplex DNA, classified in, inter alia, class 435, subclass 6.

The Group Election

By telephonic interview, Applicants elected Group I, claims 1 to 11 and 19 to 26, with traverse.

Applicants expressly reserve their right under 35 U.S.C. § 121 to file a divisional application directed to the nonelected subject matter during the pendency of this application, or an application claiming priority from this application.

The Species

The Patent Office further alleged that the claims in Groups I and II are subject to a further restriction – specifically, that Applicants are required to elect one specific sequence (see claims 2 and 13) for election (see, e.g., pages 3 to 4, paragraph 3, of the OA).

### The Species Election

By telephonic interview, Applicants elected SEQ ID NO:16, with traverse.

Applicants respectfully maintain, for reasons set forth in detail, below, that the individual sequences should be treated as though it was a species election under the procedure set forth in MPEP 809.02(a). Thus, when the elected species is held to be allowable, Applicants are entitled to consideration (examination) of additional species; if all species are held to be allowable, a generic claim should be allowed (MPEP §809.02(a); pg 800-52 to 800-53, 8<sup>th</sup> Edition, rev. 3, August 2005).

### Reasons to reconsider and withdraw restriction requirement

Applicants respectfully request the Patent Office reconsider and, in part, withdraw the restriction requirement for the following reasons:

#### *The Group Election*

Applicants respectfully request that the Group restriction be reconsidered and that Group II be rejoined to the elected Group I.

After entry of the instant amendment, claim 1 (an independent claim representative of Group I) as amended is directed to methods for identifying a molecule that modulates transcription comprising (a) providing a quadruplex DNA; and, a candidate quadruplex DNA-binding molecule, wherein the quadruplex DNA comprises the nucleotide sequence (GGA)<sub>4</sub> (SEQ ID NO:1) or the nucleotide sequence (GGA)<sub>3</sub>GG (SEQ ID NO:2), and G is guanine and A is adenine, and the quadruplex DNA is in a heptad/tetrad conformation; (b) contacting the quadruplex DNA with the candidate quadruplex DNA-binding molecule; and (c) determining the presence or absence of an interaction between the candidate quadruplex DNA-binding molecule and the quadruplex DNA, whereby the candidate molecule that interacts with the quadruplex DNA is identified as a molecule that modulates the transcription.

After entry of the instant amendment, claim 12 (an independent claim representative of Group II) as amended is directed to methods for modulating transcription, comprising (a) providing a system comprising quadruplex DNA; and, a quadruplex DNA-binding molecule, wherein the quadruplex DNA comprises a nucleotide sequence (GGA)<sub>4</sub> (SEQ ID NO:1), a nucleotide sequence (GGA)<sub>3</sub>GG (SEQ ID NO:2), or a combination thereof, and G is guanine and A is adenine, and the

quadruplex DNA is in a heptad/tetrad conformation; and (b) contacting the system comprising the quadruplex DNA with the quadruplex DNA-binding molecule, thereby modulating transcription.

Thus, the instant amendment addresses the Office's concerns that the claim may be directed to patentably distinct inventions.

Furthermore, Applicants respectfully aver that after a complete search directed to methods for identifying a molecule that modulates transcription by, inter alia, determining the presence or absence of an interaction between a quadruplex DNA-binding molecule and a quadruplex DNA, it would not be an undue burden for the Patent Office to also do a complete search for corresponding methods for modulating transcription by interacting (contacting) the quadruplex DNA-binding molecule and the quadruplex DNA.

Further evidencing that a complete search for Group I would be co-extensive with a complete search for Group II is that both groups are classified in class 435, subclass 6.

Accordingly, Applicants respectfully aver that the Office can properly rejoin all pending claims, including (amended) claims directed to methods for identifying a molecule that modulates transcription by interacting with a quadruplex DNA-binding molecule with a quadruplex DNA (Group I) with all (amended) claims directed to methods for modulating transcription by interacting a quadruplex DNA-binding molecule with a quadruplex DNA, into one restriction group (Group II).

#### *The Sequence Election*

Applicants respectfully request that all the Office examine the elected Group I methods, which comprise methods (as amended) for identifying a molecule that modulates transcription comprising, inter alia, providing a genus of quadruplex DNA molecules comprising a nucleotide sequence (GGA)<sub>4</sub> (SEQ ID NO:1), a nucleotide sequence (GGA)<sub>3</sub>GG (SEQ ID NO:2), or a combination thereof.

The Patent Office has erroneously incorporated into the genus of claim 1 the limitations (the exemplary species of quadruplex DNA molecules) of dependent claim 3. Thus, the instant restriction requirement does not follow the procedure set forth in 37 CFR §§1.141-1.146 and the corresponding sections of the MPEP for handling generic claims. According to 37 CFR §1.141, an applicant may not claim two or more independent and distinct inventions in a single application "except that more than one species of an invention . . . may be specifically claimed in different

claims in one national application, provided the application also includes an allowable claim generic to all the claimed species and all the claims to species in excess of one are written in dependent form or otherwise include all the limitations of the generic claim.” (emphasis added). Thus, where an application contains a generic claim for all of the disclosed species a restriction usually is not proper. See, e.g., R2 Medical Systems, Inc. v. Katecho, Inc., 931 F. Supp. 1397, 1436, n. 16, n. 17 (N.D. Ill. 1996). Applicants respectfully submit that because claim 1 of the instant invention is a proper generic claim (quadruplex DNA (GGA)<sub>4</sub> (SEQ ID NO:1), (GGA)<sub>3</sub>GG (SEQ ID NO:2) or a combination thereof) where all the claims to species in excess of one are written in dependent form or otherwise included all the limitations of the generic claim, the instant restriction is not proper.

The procedure for handling applications that include generic claims is set forth in 37 CFR §1.146. This rule provides that “[i]n the first action on an application containing a generic claim to a generic invention (genus) and claims to more than one patentably distinct species embraced thereby, the examiner may require the applicant in the reply to that action to elect a species of his or her invention to which his or her claim will be restricted if no claim to the genus is found to be allowable.” (emphasis added)

As stated in MPEP § 809.02(a), “[u]pon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141.” Thus, where generic claims are present, an applicant can be required to elect a species for initial examination, but the generic claims are still subject to examination to determine whether such generic claims are allowable (MPEP §809.02(a), 8<sup>th</sup> ed., rev. 2, May 2004, pg 800-49).

In the instant restriction requirement, this required procedure is not being followed. Claim 1 (of Group I, and claim 12 of Group II) is a proper generic claim within the requirements set forth in 37 CFR § 1.141. Claim 1 satisfies the definition of a generic claim as set forth in MPEP §806.04(d), in that it includes limitations that are not present in all claims that depend from it. Therefore, an election of species requirement is permissible, but a restriction requirement is not. (MPEP §806.04(d), 8<sup>th</sup> ed., rev. 3, Aug. 2005, pg 800-42, 43).

Moreover, because this “patentably distinct” species/restriction requirement splits claim 1 into multiple groups, the restriction requirement is improper as a matter of law. The courts have

long held that the section of the patent statute that authorizes restriction practice, *i.e.*, 35 U.S.C. 121, provides no legal authority for not examining a broad generic claim. See, In re Weber, 198 USPQ 328, 331 (CCPA 1978); In re Haas, 179 USPQ 623, 624-625 (In re Haas I) (CCPA 1973) and In re Haas 198 USPQ 334-337 (In re Haas II) (CCPA 1978). As stated in In re Weber:

“The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim—no matter how broad, which means no matter how many independently patentable inventions may fall within it.” 198 USPQ 328 at 334. (emphasis added)

In a case such as the instant case, where a claim is generic, a restriction requirement is tantamount to a rejection of the claim. The CCPA made this point very clear in In re Haas I:

“We find that the action taken by the examiner did in fact amount to a rejection. . . . Those claims were withdrawn from consideration not only in this application but prospectively in any subsequent application because of their content. In effect there had been a denial of patentability of the claims. Presumably only by dividing the subject matter into separate, and thus different, claims in plural applications could an examination of the patentability of their subject matter be obtained.” 179 USPQ at 625.

If the instant restriction requirement is allowed to stand, Applicants will not be accorded “the basic right of the applicant to claim his invention as he chooses.” In re Weber, 198 USPQ at 331. In In re Weber, the CCPA stated that “[a]s a general proposition, an applicant has a right to have *each* claim examined on the merits” (198 USPQ at 331, emphasis in original). The Court went on to state that:

“If . . . a single claim is required to be divided up and presented in different applications, that claim would never be considered on its merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the subgenera would be defined by the examiner rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.” 198 USPQ at 331.

Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. MPEP §803.02, 8<sup>th</sup> ed., rev. 2, May 2004, pg 800-4. Even if Applicants were to file

multiple divisional applications in addition to the instant application to obtain coverage for each of the alleged patentably distinct species, we would not have the opportunity to have our broader generic claim examined, i.e., we would not have the opportunity to have that which Applicants regard as their invention examined. The claims of the various divisional applications would be limited to the particular species set forth in the respective groups. One seeking to avoid infringement could simply choose a vector that is not specifically disclosed in the application. In effect, the restriction requirement is reading into Applicants' independent claims limitations that are not present in the claims as filed. The full scope of claim 1 as filed and pending, for example, would never be considered under the current species restriction requirement. Only the dependent claims which are set forth in the respective groups would be examined.

Applicants therefore respectfully request that the instant restriction requirement with respect to "patentably distinct species" be withdrawn and treated as though it were a species election under the procedure set forth in MPEP 809.02(a). Applicants request that, upon allowance of a generic claim, the remainder of the species be included as permitted by 37 C.F.R. § 1.141(a).

Pursuant to 37 C.F.R. § 1.144, Applicants reserve the right to petition for review of the restriction requirement at any time prior to appeal. Applicants also submit that because the instant restriction requirement is tantamount to a rejection of the generic independent claims (claim 1 of Group I, and claim 12 of Group II) the restriction requirement is appealable to the Board of Patent Appeals and Interferences. In re Haas I. If the instant restriction requirement is allowed to stand, Applicants will not be accorded "the basic right of the applicant to claim his invention as he chooses." In re Weber. It is improper for the Office to refuse to examine that which Applicants regard as their invention. MPEP §803.02, 8<sup>th</sup> ed., rev. 2, May 2004, pg 800-4.

Accordingly, Applicants respectfully request reconsideration of the restriction requirement and request that the restriction requirement with respect to the "patentably distinct species," as discussed above, be withdrawn and treated as though it were a species election under the procedure set forth in MPEP 809.02(a).

Claim objections

Claim 2 and 25 are objected to for reasons set forth on page 5, paragraphs 7 and 8, of the OA. The instant amendment addresses this issue.

Issues under 35 U.S.C. §102*Siddiqui-Jain, et al.*

Claims 1, 3, 4, 7 to 11, 19, 20 and 22 to 26, are rejected under 35 U.S.C. §102(e) as allegedly anticipated by Siddiqui-Jain, et al., U.S. patent application publication no. 2004/0005601 A1, having a priority date of April 05, 2002 (see, e.g., pages 6 to 10, paragraph 10, of the OA) (hereinafter "the '5601 publication").

The legal standard for anticipation under 35 U.S.C. §102 is one of strict identity. To anticipate a claim, a single prior source must contain each and every limitation of the claimed invention. In re Paulson, 30 F.3d 1475, 1478-79, 31 USPQ2d 1671, 1673 (Fed. Cir. 1994)(citing In re Spada, 911 F.2d 705, 708, 15 USPQ2d 1655, 1657 (Fed. Cir. 1990)). "A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). MPEP §2131; pg 2100-76, 8<sup>th</sup> ed., Rev. 3, August 2005.

Applicants respectfully aver that the limitations added to these claims in this instant amendment address the Examiner's concerns; thus, after entry of this amendment the '5601 publication is not a single prior source that contains each and every limitation of the (amended) claimed invention, and the rejection under section 102(e) can be properly withdrawn.

*Kerwin, et al.*

Claims 19 and 20 are rejected under 35 U.S.C. §102(b) as allegedly anticipated by Kerwin, et al., U.S. Patent No. 6,156,763, filed February 4, 1999 (see, e.g., pages 10 to 11, paragraph 10, of the OA) (hereinafter "Kerwin").

Applicants respectfully aver that Kerwin is not a single prior source that contains each and every limitation of the claimed invention, and note that the instant amendment further clarifies the distinction between the instant claimed methods and Kerry.



Kerry does not teach or suggest methods for identifying a molecule that modulates transcription comprising (a) providing a quadruplex DNA; and, a candidate quadruplex DNA-binding molecule, wherein the quadruplex DNA comprises the nucleotide sequence (GGA)<sub>4</sub> (SEQ ID NO:1) or the nucleotide sequence (GGA)<sub>3</sub>GG (SEQ ID NO:2), and G is guanine and A is adenine, and the quadruplex DNA is in a heptad/tetrad conformation; (b) contacting the quadruplex DNA with the candidate quadruplex DNA-binding molecule; and (c) determining the presence or absence of an interaction between the candidate quadruplex DNA-binding molecule and the quadruplex DNA, whereby the candidate molecule that interacts with the quadruplex DNA is identified as a molecule that modulates the transcription. Accordingly, the rejection of the claims under 35 U.S.C. §102(b) can be properly withdrawn.

Issues under 35 U.S.C. §103(a)

*Kerwin in view of Matsugami*

Claims 1, 3, 5 to 7, 10, 11 and 21, are rejected under 35 USC §103(a) as allegedly unpatentable over Kerwin, in view of Matsugami, et al., J. of Molec. Biol. 313:255-269, Oct. 2001 (hereinafter "Matsugami") (see paragraphs 12 and 13, pages 11 to 14, of the OA).

The Office cited Kerwin for teaching, inter alia, a method for identifying a biological molecule that modulates the biological activity of a native quadruplex DNA for identifying a molecule.

The Office notes that Kerwin is defective in that it does not teach the specific quadruplex DNA sequences (see page 12, lines 13 to 15, of the OA); does not teach that the test quadruplex DNA is in a heptad/tetrad conformation (see page 12, lines 19 to 20, of the OA); does not teach that the heptad/tetrad conformation is formed by incubation of the DNA in a potassium ion solution (see page 13, lines 1 to 3, and 6 to 7, of the OA).

However, Applicants respectfully aver that Kerwin is further defective in that it does not teach, inter alia, methods for identifying a molecule that modulates transcription comprising providing a quadruplex DNA and a candidate quadruplex DNA-binding molecule.

Matsugami is cited for, inter alia, teaching specific quadruplex DNA structures in a heptad/triad conformation (see, e.g., page 13, lines 12 to 15, of the OA).

However, Applicants respectfully submit that Matsugami does not teach or suggest methods for identifying a molecule that modulates transcription comprising providing a quadruplex DNA and a candidate quadruplex DNA-binding molecule. Accordingly, Matsugami cannot cure the defect in Kerwin. Thus, because the combination of Kerwin and Matsugami do not teach the (amended) claimed invention a *prima facie* case of obviousness has not been made and the rejection under section 103(a) can be properly withdrawn.

*Siddiqui-Jain, et al. in view of Matsugami*

Claims 5, 6 and 21, are rejected under 35 USC §103(a) as allegedly unpatentable over Siddiqui-Jain, et al., the '5601 publication, in view of Matsugami (see paragraph 14, pages 14 to 16, of the OA).

Applicants respectfully aver that the limitations added to these claims in this instant amendment address the Examiner's concerns, thus after entry of this amendment the '5601 publication and Matsugami do not teach the (amended) claimed invention. Thus, the rejection under section 103(a) based on the '5601 publication in view of Matsugami can be properly withdrawn.

Obviousness-like double patenting

Claims 1, 3 and 7 to 11 stand provisionally rejected under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1, 2, 4 and 7 to 11 of co-pending U.S. Patent Application Serial No. 10/407,449.

Applicants elect to hold this matter in abeyance until such time claims are allowed.

CONCLUSION

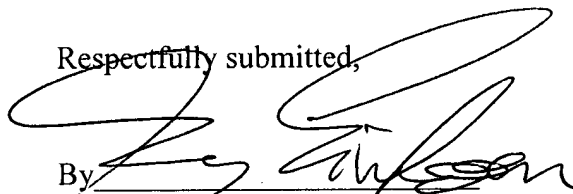
In view of the foregoing amendment and remarks, Applicants respectfully aver that the Examiner can properly withdraw the rejection of the pending claims under 35 U.S.C. §§102 and 103. In view of the above, claims in this application after entry of the instant amendment are believed to be in condition for allowance. Accordingly, the Examiner is respectfully requested to withdraw the outstanding rejections of the claims and to pass this application to issue.

In the event the U.S. Patent and Trademark Office determines that an extension and/or other relief is required, applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petitions and/or other fees due in connection with the filing of this document to Deposit Account No. 03-1952 referencing docket no. 532232000500. However, the Commissioner is not authorized to charge the cost of the issue fee to the Deposit Account.

As noted above, Applicants have requested a telephone conference with the undersigned representative to expedite prosecution of this application. After the Examiner has reviewed the instant response and amendment, please telephone the undersigned at 858 7205133.

Dated: July 10, 2006

Respectfully submitted,



By

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